

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Thomas Vanaskie  
(Ret.),  
Special Discovery Master

**THE ZHP PARTIES' SUPPLEMENTAL BRIEF IN SUPPORT  
OF THEIR MOTION TO SEAL CERTAIN DOCUMENTS AND  
DEPOSITION TRANSCRIPT EXCERPTS PURSUANT TO SPECIAL  
MASTER ORDER NO. 49**

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## I. INTRODUCTION

Plaintiffs’ claim that an internal ZHP email dated July 27, 2017 (the “July 27, 2017 email”) is a “smoking gun” that should be widely produced in the interest of public health and safety is nothing more than an attempt to sensationalize this case laid bare by the fact that all of the ZHP Parties’ valsartan was recalled from the U.S. market more than three years ago. Due to the recall, and to the FDA’s investigation into the valsartan nitrosamine impurities at issue in this case since the summer of 2018, there is no present or imminent public health and safety concern relating to any valsartan, let alone any such concern that would be ameliorated by the public disclosure of an email that, as even Plaintiffs do not dispute, is about the optimization of the manufacturing process for irbesartan.

In the absence of a present or imminent public health and safety reason, the balance for the Court in determining whether the July 27, 2017 email should remain designated “RESTRICTED CONFIDENTIAL” should tip in the favor of protection for two reasons. First, as legal matter, the July 27, 2017 email contains commercially sensitive information that, under the *Avandia* standard (discussed below), and consistent with the operative Protective Order and the Court’s ruling on May 24, 2021, should be sealed to prevent the harm resulting from disclosure to competitors. Second, Plaintiffs’ claims were purportedly brought on behalf of all pre-recall valsartan consumers in the name of public health and safety, and Plaintiffs may use

the email, subject to the rules of evidence, to prosecute their claims to that end. If, as Plaintiffs claim, the July 27, 2017 email is a “smoking gun,” which it is not, Plaintiffs may advance it as such (subject to evidentiary rules) to try to prove their claims, but nothing more in the name of public health and safety would be gained by the widespread dissemination of the email.

For these reasons, and those discussed below, the July 27, 2017 email and related deposition testimony by Dr. Min Li concerning the July 27, 2017 email should be sealed.

## **II. ARGUMENT**

### **A. The July 27, 2017 Email and Testimony of Dr. Li Are “RESTRICTED CONFIDENTIAL”**

Courts in the Third Circuit have long recognized that the presumption of public access to judicial records is not absolute. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019); *see also Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (“Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.”) (quoting *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 598 (1978)). The party seeking to overcome the presumption of access must show “that the interest in secrecy outweighs the presumption.” *Avandia*, 924 F.3d at 672 (3d Cir. 2019) (quoting *Bank of Am. Nat’l Tr. & Sav. Ass’n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)).

To do so, the movant must demonstrate ““that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.”” *Id.* (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)); *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984)); *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 (3d Cir. 1994).

This balancing test is echoed by this Court’s local rules, which permit otherwise public documents to be filed and maintained under seal upon a showing of good cause. *See* D.N.J. L. Civ. R. 5.3(c); *Vista India, Inc. v. Raaga, LLC*, No. 07-cv-1262, 2008 WL 834399, at \*3 (D.N.J. Mar. 27, 2008). The movant must demonstrate that the following factors weigh in favor of sealing the information at issue: (1) the nature of the materials or proceedings at issue; (2) the legitimate private or public interest which warrants the relief sought; (3) the clearly defined and serious injury that would result if the relief sought is not granted; and (4) why a less restrictive alternative to the relief sought is not available. *See* D.N.J. L. Civ. R. 5.3(c)(3). In considering such applications, the Court should balance factors for and against access, including whether: (1) the information to be protected includes genuinely confidential information such as proprietary materials, or information that could give unfair advantage to a competitor; (2) the documents were produced under the auspices of an existing confidentiality order upon which the parties relied; and (3) whether the movant is a private entity, not a public official seeking protection

from “legitimate public scrutiny.” *See Pansy v. Stroudsburg*, 23 F. 3d 772, 788-91 (3d Cir. 1994). The scale is tipped in favor of confidentiality where the parties relied on a prior confidentiality order. *See, e.g., Rutigliano v. Appleton Papers, Inc.*, No. 90-1432, 2000 WL 1705152 at \*5 (D.N.J. Oct. 6, 2000) (public disclosure in product liability action should not be compelled where defendant produced material in reliance on a confidentiality order).

As set forth below, the ZHP Parties satisfy the criteria for sealing under Local Rule 5.3(c) and Third Circuit’s precedents.

**1. The ZHP Parties Have a Legitimate Interest in Maintaining the Confidentiality of the July 27, 2017 Email and Related Testimony**

This Court, and courts construing New Jersey law, have recognized the need to protect from disclosure confidential research, development, product testing, and other trade secret information involving pharmaceutical manufacturers to protect a litigant’s standing in the marketplace, including API manufacturing process and product optimization procedures. *See In re: Valsartan, Losartan and Irbesartan Prods. Liab. Litig.*, MDL No. 2875, dated May 24, 2021 at 18-19 (granting motion to seal internal notes regarding ZHP’s process optimization strategies where disclosure “would result in significant competitive harm by allowing [competitors] to benefit from ZHP’s proprietary research and development while the FDA restricts ZHP from exporting its products into the U.S. market.”); *see also Impax Labs., Inc.*



*v. Zydus Pharm. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at \*3 (D.N.J. Dec. 6, 2018) (“this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers”); *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d at 667 (affirming denial of motion to unseal documents containing defendant’s ANDA, DMF, processes, formulations, and testing); *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 U.S. Dist. Lexis 212, at \*6-8 (D.N.J. Jan. 3, 2017) (sealing confidential manufacturing and research and development processes and information).

The need to protect competitively sensitive information is essential in the pharmaceutical industry where courts have recognized the need to protect from disclosure competitively sensitive and confidential business information to preserve, and not diminish, a litigant’s standing in the marketplace. *See In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 13-md-2452, 2021 WL 873290, \*2 (S.D. Cal. Mar. 9, 2021) (granting drug manufacturer’s omnibus motion to seal internal regulatory and safety analyses where “[d]efendants’ interest in safeguarding these

competitive business materials overcomes the general presumption of public access”).<sup>1</sup>

The July 27, 2017 email and related testimony of Dr. Li contain commercially sensitive, non-public, information regarding the ZHP Parties’ proprietary process optimization efforts and related testing as to irbesartan API. *See* Declaration of Dr. Min Li (the “Dr. Li Decl.”) at ¶ 6. The July 27, 2017 email, which was not intended for external dissemination, was part of a project by ZHP to improve its manufacturing processes for irbesartan API. *See* Dr. Li Decl. at ¶¶ 3-5. It represents the concerted time, efforts, and expenditures by the ZHP Parties’ technical analysis department (CEMAT) and the Technology Department of its Chuannan facility, to test and improve the process by which it manufactured irbesartan API at the research and development stage. *See id.* at ¶¶ 4-5.

The July 27, 2017 email focuses on (1) proprietary technical improvements by the Chuannan facility’s Technical Department regarding irbesartan, (2) the Technical Department’s communications with CEMAT regarding technical changes

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<sup>1</sup> Plaintiffs’ attempts to distinguish the authorities on which the ZHP Parties rely is limited to a single footnote, characterizing them as inapplicable because they were “unpublished and unopposed.” *See* Opp. at 13 n.3. But the fact that the motions to seal in those instances were unopposed does not obviate a movant’s burden to demonstrate, *independently*, that its need to maintain the confidentiality of its proprietary information outweighs the public’s interest in accessing judicial records. *See* L. Civ. R. 5.3(c)(3).

observed during the attempted process improvements, and (3) CEMAT's subsequent analysis of these changes. *See* Dr. Li Decl. at ¶ 6. The July 27, 2017 email also proposes additional testing by CEMAT to simulate the attempted processes and resulting conditions, and to verify the results. *See id.* at ¶ 7. As emphasized by the declaration of Dr. Li, information regarding the results of the ZHP Parties' internal process and product optimization efforts with respect to irbesartan is highly confidential, non-public, and competitively sensitive. *See* Dr. Li Decl. at ¶¶ 8-10 (ECF No. 1584-5).

Furthermore, the ZHP Parties produced this proprietary information in reliance on the Court's Protective Order. The ZHP Parties designated the July 27, 2017 email as "RESTRICTED CONFIDENTIAL" based on the ZHP Parties' good faith belief that disclosure would impair the ability of ZHP to compete in the highly competitive pharmaceutical API and finished dose product market. *See* ECF No. 1661 at ¶ 9(M) (defining "RESTRICTED CONFIDENTIAL" as "[d]ocuments a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including **proprietary manufacturing and production information (including formulation).**") (emphasis added); *see also id.* at ¶ 9(B) (noting that nothing herein shall be construed to prevent a Producing Party from designating documents as "CONFIDENTIAL INFORMATION" in order to expedite the flow of discovery and facilitate discovery

in these consolidated actions.”). Likewise, the ZHP Parties designated portions of Dr. Li’s testimony as “RESTRICTED CONFIDENTIAL” pursuant to Paragraph 17(B) of the Protective Order because they disclosed the contents of the July 27, 2017 email. *See* ECF. No. 1661, ¶ 17(b) (permitting designation of portions of any deposition transcript in which documents containing “PROTECTED INFORMATION” are discussed).

**2. The ZHP Parties Would Sustain a Clearly Defined and Serious Injury if the July 27, 2017 Email and Related Testimony Were Disclosed**

The clearly defined and serious injury that would result from disclosure of the July 27, 2017 email and related testimony is that the ZHP Parties would sustain significant competitive harm as a result of the disclosure to their competitors of their proprietary API process optimization strategies, testing and procedures relative to irbesartan, a widely prescribed and used antihypertensive medication with many generic competitors.

It is well-known that the pharmaceutical industry is a “highly competitive market where companies routinely attempt to discover a possible advantage over their competitors.” *See Public Citizen Health Research Grp. v. NIH*, 209 F. Supp. 2d 37, 47 (D.D.C. 2002); *see also United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165 GHK (SS), 2016 WL 6542729, at \*4 (C.D. Cal. Mar. 14, 2016) (“In a field as competitive and technical as the pharmaceutical industry, success or failure

will turn in large measure on innovation . . . .”) (internal citation omitted). This Court has previously granted motions to seal confidential and proprietary information where the disclosure of such information would give competitors an unfair business advantage. *See* May 24, 2021 Order at 18-19; *see also Novartis Pharms. Corp. v. Mylan Pharms., Inc.*, No. 06-2885 (MLC), 2008 WL 11383884 at \*1-2 (D.N.J. Oct. 31, 2008) (granting motion to seal where Novartis had a legitimate business interest in preventing the disclosure of confidential and proprietary information, and where disclosure of such information would result in competitors gaining an unfair competitive advantage in the marketplace).

The disclosure of the ZHP Parties’ proprietary irbesartan optimization efforts would result in significant competitive harm to the ZHP Parties by allowing the ZHP Parties’ direct competitors to benefit from the ZHP Parties’ research and development, and testing directed to optimizing irbesartan’s manufacturing processes while the FDA restricts ZHP from exporting its products into the U.S. market, awarding a significant competitive advantage to the ZHP Parties’ competitors. *See* Dr. Li Decl. at ¶¶ 8-10. Such disclosure may well impede the ZHP Parties’ ability to re-enter the U.S. market following the removal of the import ban. *See id.* Thus, the disclosure of the July 27, 2017 email would be of significant competitive value to the ZHP Parties’ many competitors in the generic drug marketplace.

**3. There Is No Less Restrictive Alternative Available to Sealing the July 27, 2017 Email and Related Testimony**

There is no less restrictive alternative available than to seal the July 27, 2017 email and the related testimony of Dr. Li. The ZHP Parties have carefully analyzed these documents, and have sought to redact only the materials that disclose or reference the contents of the July 27, 2017 email, which the ZHP Parties previously designated as “RESTRICTED CONFIDENTIAL.” *See id.*

**4. There Is No Prior Order Sealing the July 27, 2017 Email and Related Testimony**

There are no prior Orders sealing the July 27, 2017 email or related testimony.

**B. Plaintiffs’ Objections to Sealing the July 27, 2017 Email and Related Testimony are Unpersuasive and Meritless**

Plaintiffs argue that the July 27, 2017 email and related testimony should be de-designated due to health and safety issues, and because Plaintiffs dispute whether the documents contain sufficient proprietary information to outweigh the public’s right to access judicial records. *See* ECF No. 1392 at 4, 11 and ECF No. 1652 at 1. But Plaintiffs’ unsupported assertions are not enough to outweigh the ZHP Parties’ interest in maintaining the confidentiality of the July 27, 2017 email and related testimony, particularly where there is no obstacle to Plaintiffs’ using either document, subject to the rules of evidence, to prosecute their claims against the ZHP Parties in the purported name of public health and safety.

**1. Plaintiffs Have Failed to Articulate How the July 27, 2017 Email or Related Testimony Contain “Vital Health and Safety Information”**

Contrary to Plaintiffs’ rhetoric, granting the ZHP Parties’ motion to seal the July 27, 2017 email and related testimony would have no adverse impact on the public’s awareness of health or safety issues for two reasons. First, the July 27, 2017 email does not contain any information regarding nitrosamine impurities identified in the ZHP Parties’ valsartan intended for the U.S. market, despite Plaintiffs’ persistent mischaracterizations.<sup>2</sup> Second, Plaintiffs have purported to bring this litigation in the name of public health and safety on behalf of all consumers of valsartan-containing drugs prior to the 2018 recall. *See* Third Amed. Consol. Econ. Loss Class Action Compl. at ¶ 4 (ECF No. [1708](#)). If the July 27, 2017 email is as pivotal as Plaintiffs allege (and it is not), then maintaining its confidentiality in no way impedes Plaintiffs’ ability to use it to try to prove their claims against the ZHP Parties. The ZHP Parties cannot be said to be “hiding” anything related to the July 27, 2017 email, as Plaintiffs wrongly assert, *see* ECF No. 1652 at 13, because the ZHP Parties produced it in the normal course of discovery, and Plaintiffs had the

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<sup>2</sup> As the ZHP Parties advised this Court during the September 10 hearing—which the parties conducted *in camera* specifically to discuss the contents of the July 27, 2017 email (*see* ECF Nos. 1584-3 at ¶ 30 and 1702 at 2), Plaintiffs have persistently mischaracterized the contents of the July 27, 2017 email to exaggerate its importance and to bolster their case. *See* Sept. 10 Hr’g Tr. at 21:1-5.

opportunity to question no fewer than five of the ZHP Parties' witnesses about it during their depositions (including during the 30(b)(6) deposition of Dr. Li). Maintaining the confidentiality of the July 27, 2017 email simply and fairly balances the ZHP Parties' need to protect their commercially sensitive information with the Plaintiffs' supposed need to use it (subject to the rules of evidence) in order to prosecute their claims.

Plaintiffs' mischaracterizations appear intended to distract the Court from the shallowness of their objection.<sup>3</sup> Plaintiffs neglect to identify a single case in support of their position that a movant's interest in maintaining the confidentiality of its proprietary manufacturing process optimization procedures is outweighed by unspecified health and safety concerns. Nor do Plaintiffs make any attempt to engage with any of the factors to be considered in determining whether to seal judicial records. *See Avandia*, 924 F.3d at 671. Plaintiffs do not allege, for example, nor could they, that the July 27, 2017 email reveals information regarding the ZHP

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<sup>3</sup> As the Court has acknowledged, Plaintiffs have repeatedly asserted health-and-safety objections in seeking to publicize the ZHP Parties' proprietary, non-public information, and the Court has advised Plaintiffs to assert this objection with greater specificity. *See* Case Management Conference Tr. dated Oct. 27, 2021 at 22:2-9 ("I'm hoping, from the Plaintiffs' perspective, or speaking to you as the Plaintiffs' counsel, and speaking to all Plaintiffs' counsel, that you just don't rely upon the assertion about—and this is, it's a very important matter and it does involve public health and safety, I understand that; but I hope there's a little more meaningful discussion or much more meaningful discussion than simply making that assertion").



Parties' manufacturing and testing processes for valsartan API intended for distribution in the United States. Nor do Plaintiffs allege that the July 27, 2017 email summarizes, contextualizes, or analyzes any alleged manufacturing or testing processes or concerns that resulted in the NDMA impurity in valsartan, or relate to the recall. Finally, Plaintiffs do not allege that the July 27, 2017 email contains information that relates to any current or imminent health and safety concern, nor could they given the recall of the valsartan in 2018 and the FDA's investigation into the alleged nitrosamine impurities.

Conversely, no fewer than five of the *Avandia* factors weigh against disclosure of the July 27, 2017 email, including (1) Plaintiffs' ability to use the July 27, 2017 email to prosecute their claims and advance any related health and safety interests; (2) the non-public and proprietary nature of the process optimization and testing information at issue; (3) the intent of the July 27, 2017 email's author, Jinsheng Lin, not to disseminate the information beyond the ZHP Parties; (4) the fact that the ZHP Parties designated not only the July 27, 2017 email, but any related deposition and/or hearing excerpts as "RESTRICTED CONFIDENTIAL" pursuant to the Court's Protective Order; and (5) the non-speculative risk of competitive harm to the ZHP Parties as a result of disclosure.

**2. Plaintiffs' Remaining Objections to Sealing the July 27, 2017 Email and Related Testimony Are Unfounded**

Plaintiffs further argue that the public's interest in accessing court records outweighs any interest by the ZHP Parties in maintaining their confidential designation (ECF No. 1392 at 8). This contention, as Plaintiffs' others, is meritless. The Third Circuit has consistently acknowledged, the public's right to access judicial records may be rebutted where, as here, a movant demonstrates that its interest in maintaining the confidentiality of its information outweighs the public's right to access. *See, e.g., Avandia*, 924 F.3d at 672; *Littlejohn*, 851 F.2d at 678 (2019). Similarly, the sealing of confidential documents and information is an accepted practice in the District of New Jersey. *See In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 653 (D.N.J. 2004).

Similarly, Plaintiffs' assertion that the July 27, 2017 email lacks "proprietary information of any use to ZHP or its competitors" (ECF No. 1652 at 1) is patently false. The July 27, 2017 email describes the ZHP Parties' process optimization methods as to the manufacture of irbesartan, including observations as to technical changes observed, and proposed testing to examine and analyze these results. *See* Dr. Li Decl. at ¶¶ 8-9. Such information, if disclosed to the ZHP Parties' competitors, could be utilized in their own manufacturing and testing procedures for this product, allowing them to reap the benefits of the ZHP Parties' confidential, proprietary research.

Lastly, Plaintiffs speculate as to the ZHP Parties’ “true” motives in seeking to maintain the confidentiality of the July 27, 2017 email and related testimony. *See* ECF No. 1392 at 8-9 and ECF No. 1652 at 1 (alleging that the ZHP Parties “fear[] public disclosure” and are engaged in “nothing more than a desperate attempt at damage control.”). But these claims have no basis in fact where, as demonstrated *supra* 11, these claims do not reflect the ZHP Parties’ view of the July 27, 2017 email, but Plaintiffs’ own deliberate mischaracterizations.

### III. CONCLUSION

For the foregoing reasons, and those asserted in its Motion, the ZHP Parties respectfully request that the Court grant the ZHP Parties’ Motion to Seal the July 27, 2017 email and related portions of the deposition testimony of Dr. Li.

Dated: November 8, 2021

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Kelly A. Bonner Esq., hereby certify that a complete copy of the foregoing ZHP Parties' Supplemental Brief in Support of Their Motion to Seal Certain Documents and Deposition Transcript Excerpts Pursuant to Special Master Order No. 49 has been filed electronically on the docket in this matter, and is available for viewing and downloading from the ECF system. This document is being served upon the following counsel on November 8, 2021 through the ECF system, and a courtesy copy is being sent by email:

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